PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12809PC2	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. **PCT**/AU2004/001839	International filing date *(day/month/year)* 31 December 2004	Priority date *(day/month/year)* 31 December 2003
International Patent Classification (IPC) or national classification and IPC		
Applicant AYZALA PTY LTD et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☐ *(sent to the applicant and to the International Bureau)* a total of 9 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand 24 June 2005	Date of completion of this report
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **MATTHEW FORWARD** Telephone No. (02) 6283 2606

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001839

Box No. I Basis of the report

1. With regard to the **language,** this report is based on:

[X] The international application in the language in which it was filed

[ ] A translation of the international application into , which is the language of a translation furnished for the purposes of:

[ ] international search (under Rules 12.3(a) and 23.1 (b))

[ ] publication of the international application (under Rule 12.4(a))

[ ] international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

[ ] the international application as originally filed/furnished

[X] the description:

pages **1-2, 7-15** as originally filed/furnished
pages **3-6, 6a, 16** received by this Authority on **30 March 2006** with the letter of 30 March 2006
pages* received by this Authority on with the letter of

[X] the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages **17-19** received by this Authority on **15 March 2006** with the letter of 14 March 2006
pages* received by this Authority on with the letter of

[X] the drawings:

pages **1/14-14/14** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

[ ] a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

4. [ ] This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

[ ] the description, pages
[ ] the claims, Nos.
[ ] the drawings, sheets/figs
[ ] the sequence listing *(specify)*:
[ ] any table(s) related to the sequence listing *(specify)*:

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001839

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos: **26-30**

because:

☒ the said international application, or the said claims Nos. **26-30**
relate to the following subject matter which does not require an international preliminary examination *(specify)*:

Claims 26-30 define simply a method presenting information regarding the priority of a sample and as such do not comply with rule 67.1 (v) of the PCT.

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos.
are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos.
are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*

☐ no international search report has been established for said claim Nos.

☐ A meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ Furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ Furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ Pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ A meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001839

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	**1-25**	**YES**
	Claims		**NO**
Inventive step (IS)	Claims	**1-25**	**YES**
	Claims		**NO**
Industrial applicability (IA)	Claims	**1-25**	**YES**
	Claims		**NO**

2. Citations and explanations (Rule 70.7)

The following documents were cited in the International Search report as a basis for a novelty or inventive step argument:

D1: EP 0983761 (BROSELOW)

D2: "Colour Coding System" California Cryobank Sperm Bank

D3: US 6428640 (STEVENS et al)

D4: US 2003/0206831 (STEVENS et al.)

The present application defines a specimen container comprising a body, a lid and a continuous coloured indicator band which extends around the entire circumference of the body and is positioned such that it is visible when the lid is placed on the container or when the container is placed in a rack. Essential to the invention is the time the indicator band is incorporated into the specimen container, it must be before the specimen is placed within the container.

Novelty
Claims 1-25 meet the criteria set forth in PCT Article 33(2) for novelty. The prior art published before the priority date does not disclose a specimen container comprising a coloured indicator band which extends around the whole circumference of the body and is incorporated into the body before the specimen is placed in the container.

Inventive StepD1 discloses a method of determining the correct dosage for a particular patient based on a colour coding system. The coloured labels are fixed to the specimen container correlate to a particular dosage based upon the weight of the patient and may also include additional patient information.

D2 discloses a two-way colour coding system used to identify samples. The first uses a coloured lid to identify racial group and the second is a green band below the label to indicate whether the specimen has been washed. From the photo shown on the webpage cited it is clear that this band extends mostly around the body of the container. This identification is in the form of a sticker that adheres to the container. When the colour coded vials are placed in the trays as shown the indicator band is visible. This quality assurance method is currently used in the California Cryobank laboratory which establishes it as a method that function within a lab environment.

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of: **Box V (2)**

D3 discloses a label system for attaching to specimen containers information relating to the sample held within the container. As such the label is designed to be removed from the container and this information could include information relating to the prioritising of the sample.

D4 discloses a specimen label comprising a barcode and human readable portion and a removable tab portion. The container may be electronically linked to the laboratory.

D2 is considered to be the closest citations described here and as this document does not include an indicator which is incorporated with the body of the container prior to the sample being placed within the container the invention as defined is considered to be both novel and inventive. As such claims 1-25 meet the criteria set out in PCT Article 33(3) with regard to the requirement of Inventive Step.